K100349

MAY 21 2010

510(k) Summary

Submitter Information

Company:	Johnson & Johnson Vision Care, Inc. 7500 Centurion Parkway Suite 100 Jacksonville, FL 32256
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Date Prepared:	February 8, 2010

Identification of the Device

Common Name:	Soft Contact Lens
Device Name:	VISTAKON® (narafilcon B) Contact Lens
Classification Name:	Soft Hydrophilic Contact Lens, Daily Wear
Device Classification:	Class II, 21 CFR 886.5925 (b) (1).

Predicate Device(s)

Material

VISTAKON® (narafilcon A) Contact Lens – K073485
(FDA Group I; low water, nonionic polymer)

Indication, Wear Schedule

VISTAKON® (etafilcon A) Contact Lenses – K962804
(Daily wear, single use)

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Description of Device

- The VISTAKON® (narafilcon B) Contact Lens Visibility Tinted with UV Blocker is available as a spherical lens, multifocal lens, toric lens, and toric-multifocal lens.
- The lenses are made of a silicone hydrogel material containing an internal wetting agent.
- The VISTAKON® (narafilcon B) Contact Lens is tinted blue using Reactive Blue Dye #4 to make the lens more visible for handling.
- A benzotriazole UV absorbing monomer is used to block UV radiation. The transmittance characteristics are less than 1% in the UVB range of 280 – 315nm and less than 10% in the UVA range of 316 – 380nm.
- The VISTAKON® (narafilcon B) Contact Lens is a hemispherical or hemitoric shell.
- The lens is supplied in a sterile state, packaged in a buffered saline solution with methyl ether cellulose.
- The composition of the lens is 52% narafilcon B and 48% water by weight when hydrated and stored in the buffered saline solution.

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Indications for Use

Lens Design	Indication
Spherical	The VISTAKON® (narafilcon B) Contact Lens is indicated for daily wear single use only for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who may have 1.00D or less of astigmatism.
Multifocal	The VISTAKON® (narafilcon B) Contact Lens is indicated for daily wear single use only for the optical correction of distance and near vision in presbyopic, phakic or aphakic persons with non-diseased eyes who may have 4.00D of ADD power or less and 0.75D of astigmatism or less.
Toric	The VISTAKON® (narafilcon B) Contact Lens is indicated for daily wear single use only for the optical correction of visual acuity in phakic or aphakic persons with non-diseased eyes that are hyperopic or myopic and may have 4.00D of ADD power or less and 10.00D or less of astigmatism.
Multifocal Toric	The VISTAKON® (narafilcon B) Contact Lens is indicated for daily wear single use only for the optical correction of distance and near vision in presbyopic phakic or aphakic persons with non-diseased eyes who may have 4.00D of ADD power or less and 10.00D of astigmatism or less.

- VISTAKON® (narafilcon B) Contact Lenses contain a UV Blocker to help protect against transmission of harmful UV radiation to the cornea and into the eye.

- The Eye Care Professional should prescribe the lenses for daily wear single use only. The lenses are to be discarded upon removal; therefore, no cleaning or disinfection is required.

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Technological Characteristics

The technological characteristics of the VISTAKON® (narafilcon B) Contact Lenses are compared to the characteristics of the predicate device, VISTAKON® (narafilcon A) Contact Lens, in the following tables.

Material Comparison		
	Predicate Device	**Subject Device**
Product Name	VISTAKON® (narafilcon A) Contact Lens	VISTAKON® (narafilcon B) Contact Lens
Material USAN Name	narafilcon A	narafilcon B
510(k) Number	K073485	TBD - This submission
FDA Category (Group)	Group I	Group I
Manufacturing Method	Molded	Molded
Sterilization	Moist Heat	Moist Heat
Packaging	Blister	Blister
Visibility Tint	Blue	Blue

Parameter Comparison				
	Predicate Device VISTAKON® (narafilcon A) Contact Lens – K073485		**Subject Device VISTAKON® (narafilcon B) Contact Lens**	
	Measured	**Labeled**	**Measured**	**Labeled**
Water Content, %	47	46	48	48
Refractive Index @ 20°C	1.40	1.41	1.41	1.41
Dk, edge corrected	96	100	52	55
Base Curve, mm	8.53	8.5	8.49	8.5
Diameter, mm	14.26	14.2	14.19	14.2
Power, D	-0.92	-1.00	-0.98	-1.00

*Polarographic Method, Dk units: 10^{-11} $(cm^2/sec)(ml\ O_2/ml \times mmHg)$

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Non-clinical Testing

A series of *in-vitro* and *in-vivo* preclinical toxicology and biocompatibility tests were performed to assess the safety and effectiveness of the contact lens. All tests were conducted in accordance with the GLP regulation (21 CFR Part 56) or according to valid scientific protocols.

The results of the non-clinical testing/evaluation demonstrate that:

- the lens material and/or extracts are non-toxic, non-irritating and non-sensitizing under the experimental conditions; and
- the lens physical and material properties are consistent with currently marketed lenses.

Clinical Testing

A one-month clinical study was completed to evaluate the safety and efficacy of the VISTAKON® (narafilcon B) Contact Lens for single use daily wear only.

The study evaluated 48 subjects with a 1:1 ratio between the test lens and the control lens (*1-DAY* ACUVUE® Brand Contact Lenses). The primary endpoints were slit lamp findings, symptoms, problems and complaints, visual acuity and average wear time. Additional parameters measured included adverse reactions, keratometry changes, reasons for discontinuation, and the number and reasons for unscheduled lens replacements.

The clinical evaluation demonstrated similar overall performance in the clinically relevant areas of vision and health as compared to concurrent controls when used under daily wear single use conditions.

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Conclusions Drawn from Studies

Validity of Scientific Data	A contract laboratory under Good Laboratory Practice Regulations conducted toxicology studies. Microbiology, chemistry, shelf-life stability, and leachability studies were conducted by VISTAKON® laboratories and followed scientific protocols. The data were determined to be scientifically valid under 21 CFR 860.7.
Substantial Equivalence	Information presented in this Premarket Notification establishes that the VISTAKON® (narafilcon B) Contact Lens is as safe and effective as the predicate device when used in accordance with the labeled directions for use and for the requested indication.
Risk and Benefits	The risks of the subject device are the same as those normally attributed to the wearing of soft (hydrophilic) contact lenses on a daily wear single use basis. The benefits to the patient are the same as those for other soft (hydrophilic) contact lenses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-0609
Silver Spring, MD 20993-0002

Johnson & Johnson Vision Care, Inc.
C/O Catherine C. Dillon
Regulatory Affairs
7500 Centurion Parkway, Suite 100
Jacksonville, FL 32256

MAY 21 2010

Re: K100349
Trade/Device Name: VISTAKON® (narafilcon B) Contact Lenses
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) contact lens
Regulatory Class: Class II
Product Code: LPL
Dated: May 4, 2010
Received: May 5, 2010

Dear Ms. Dillon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Alexander

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological, and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K100349

Device Name: VISTAKON® (narafilcon B) Contact Lens Visibility Tinted, with UV Blocker

Indications for Use:

The VISTAKON® (narafilcon B) Soft Contact Lens (spherical) is indicated for daily wear single use only for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who may have 1.00D or less of astigmatism.

The VISTAKON® (narafilcon B) Multifocal Soft Contact Lens is indicated for daily wear single use only for the optical correction of distance and near vision in presbyopic, phakic or aphakic persons with non-diseased eyes who may have 4.00D of ADD power or less and 0.75D of astigmatism or less.

The VISTAKON® (narafilcon B) Toric Soft Contact Lens is indicated for daily wear single use only for the optical correction of visual acuity in phakic or aphakic persons with non-diseased eyes that are hyperopic or myopic and may have 10.00D or less of astigmatism.

The VISTAKON® (narafilcon B) Multifocal-Toric Soft Contact Lens is indicated for daily wear single use only for the optical correction of distance and near vision in presbyopic phakic or aphakic persons with non-diseased eyes who may have 4.00D of ADD power or less and 10.00D of astigmatism or less.

VISTAKON® (narafilcon B) Contact Lenses contain a UV Blocker to help protect against transmission of harmful UV radiation to the cornea and into the eye.

The Eye Care Professional should prescribe the lenses for daily wear single use only. The lenses are to be discarded upon removal; therefore, no cleaning or disinfection is required.

Prescription Use X And/Or Over the Counter Use _____
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Karen Waluntas

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K100349